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To: Max H. Dodson, Assistant Regional Administrator
Ecosystems, Protection and Remediation

From: Mary Goldade, Regional Superfund Chemist

Subject: Review of RJ Lee Group, Inc. Laboratory Audit Reports and EPA Headquarters Memorandums Indicating RJ Lee Group, Inc. Laboratories' Capabilities for Asbestos Testing

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Background

In June 2003 the former Office of Emergency and Remedial Response (OERR), distributed an Agency-wide directive signed by Director Michael B. Cook, advising Superfund Regional Project Managers to review "any site management decision for asbestos contaminated sites where analytical data generated by asbestos testing laboratories associated with RJ Lee Group, Inc. were critical." The memo cites serious deficiencies in laboratory analysis and documentation procedures in asbestos testing specific to the San Leandro, California location. Based upon the "questionable practices observed at the San Leandro facility", the memo further recommended Regions review asbestos testing data generated by any RJ Lee Group, Inc. laboratory.

Recently, the renamed Office of Superfund Remediation and Technology Innovation (OSRTI), provided an updated memo (again signed by Director Michael B. Cook). In the July 30, 2004 memorandum the results of a follow-up audit of the San Leandro facility and of a new on-site audit of the corporate RJ Lee Group, Inc. testing facility in Monroeville, Pennsylvania are summarized. The updated information indicated that the RJ Lee Asbestos Testing Laboratories

were "capable of performing satisfactory asbestos analyses for Superfund". With respect to the San Leandro, California, facility, the improvements described in the 2004 OSRTI memo indicated striking differences from the audit performed almost 3 years prior. Given the apparent inconsistencies between them, we undertook a thorough review of each of the laboratory audit reports that formed a basis for the memos issued by Director Michael B. Cook at EPA Superfund Headquarters (OERR/OSRTI).

Objective

The purpose of this memo is to report the detailed results of a side-by-side review of the laboratory audit reports and the subsequent memorandums issued by EPA Superfund Headquarters (OERR/OSRTI).

Documentation Reviewed

Document review included the following:

1) *Summary On-site Audit Report for RJ Lee Group, Inc. Bay Area Laboratory*; San Leandro, CA (IT Corporation, May 1, 2001)
2) *Summary Asbestos On-site Audit Report for RJ Lee Group, Inc. Bay Area Laboratory*; San Leandro, CA (Shaw Environmental, Inc., February 11, 2004)
3) *Summary Asbestos On-site Audit Report for RJ Lee Group, Inc.*; Monroeville, PA (Shaw Environmental, April 6, 2004)
4) Memorandum dated June 19, 2003 submitted by the Office of Emergency and Remedial Response. Subject: *RJ Lee Asbestos Testing Laboratories*
5) Memorandum dated July 30, 2004 submitted by the Office of Superfund Remediation and Technology Innovation. Subject: *Update on RJ Lee Asbestos Testing Laboratories*

Observations

The audit reports for each RJ Lee Group, Inc. facility were reviewed individually to determine laboratory adequacy. Observations pertaining to the laboratories' ability to perform satisfactory asbestos analyses for Superfund are provided below. Additionally, my comments on the EPA Superfund Headquarters' memos regarding the use of RJ Lee Group, Inc., Laboratories as they relate to the audits are summarized as appropriate.

Section 1 RJ Lee, Inc.—San Leandro Facility

Two on-site audit reports were prepared for the San Leandro facility, one in May 2001 and the other in February 2004. Both audit reports were reviewed in detail and they provide an understanding of the laboratory's approach to the technical and quality operations of asbestos testing at the San Leandro facility over time.

Section 1.1 May 2001 Audit Report for San Leandro

In April 2001 EPA's Analytical Services Branch (ASB) first visited the RJ Lee Group Inc.—San Leandro facility at the request of EPA Region 9. A report for the audit was prepared in May 2001. For the purposes of this memo, the audit will be referred by the audit report date: May 2001. According to the audit report, the issue of interest was discrepancies in reported analytical results between RJ Lee and another laboratory serving as a quality control (QC) laboratory. As such, while the May 2001 audit appears to review overall laboratory practices in the areas of sample custody, handling, tracking, and storage, only one analytical method and applicable documentation practices were evaluated. These related to the CARB 435 method by polarized light microscopy (PLM). In spite of the limited scope of the audit, the report outlines a significant list of deficiencies in the areas of: sample custody, handling, storage and tracking; analytical procedure; documentation; and quality assurance (QA) practices. For every finding the auditors provided a recommendation to facilitate improvement. The audit report concludes: "The overall evaluation of the laboratory revealed procedural weaknesses with regard to a lack of an on-site QA/QC program, compliance with laboratory SOPs and methodology, sample handling, record keeping, and incomplete documentation of analytical results." This statement along with the audit findings leaves little room for conjecture. It is clear that serious deficiencies existed which compromised the ability of the RJ Lee Group, Inc. –San Leandro to perform asbestos testing on the method evaluated.

The audit also states: "The majority of the staff were very cooperative, and readily answered all questions posed by the on-site audit team. The management of the laboratory was responsive to the identified observations and appeared to be dedicated to correcting **all** of the audit observations" (emphasis added). Having audited laboratories myself, I appreciate auditees' cooperative behavior; however, I do not recognize their courtesy to the audit team as an indicator of a laboratory's ability to perform accurate asbestos analysis or carry through on corrective actions. What I do look for is the extent to which the laboratory attempted to make improvements on the previous audit findings. This is because laboratories are expected to maintain a QA/QC program that engenders a culture of continuous improvement. That is, we expect the laboratories to take corrective action in response to audit findings.

Section 1.2 June 2003 OERR Memo

On June 19, 2003 OERR provided an advisory to Superfund Regional Project Managers recommending that they "thoroughly review any site management decision for asbestos contaminated sites where analytical data generated by asbestos testing laboratories associated with RJ Lee Group, Inc. were critical." The memo notes the details surrounding the ASB audit of RJ Lee Group's San Leandro facility. A few of the findings from the May 2001 are provided in the June 2003 OERR memo to serve as an indication of the issues pertaining to the San Leandro facility. The findings that are summarized in the 2003 OERR memo accurately depict the contents of the May 2001 audit report. As issued, therefore, and based upon the caveats placed within, the 2003 OERR memo appears accurate and appropriately represented by

information presented in the audit report.

Section 1.3 February 2004 Audit Report for San Leandro

In December 2003 EPA's ASB returned to RJ Lee Group, Inc.—San Leandro facility. A report for the audit was prepared in February 2004. For the purposes of this memo, the audit will be referred by the audit report date: February 2004. While certainly not a contractual requirement, the reason for the revisit is not given in the report. The scope of the audit was larger than in 2001 including evaluations of several analytical techniques including PLM, PCM, and TEM. As part of Region 8's review, the February 2004 audit report was assessed for several components. These include an assessment of: the facility's ability to perform asbestos analysis; the adequacy of the supporting QA/QC program; whether the laboratory corrected deficiencies identified in the previous audit; and whether the audit revealed new laboratory deficiencies.

Correction of Past Deficiencies

Thirteen (13) observations were cited in the February 2004 audit report. While this number is half of that listed in the audit from 3 years prior, it is notable that 8 of the 13 observations described in the February 2004 audit report were the same findings documented in May 2001. Some of the same significant deficiencies noted were in the areas of: sample custody, handling, storage and tracking; analytical procedure; documentation; and QA practices. Among the most notable repeat deficiencies was in the stereomicroscopic and PLM analyses. The lab technicians still were not consistently identifying the optical properties of the fibers detected. Also key was the repeat finding that semi-annual internal audits performed by RJ Lee Group, Inc.'s Quality Assurance Coordinator and the associated response and/or corrective actions taken in response to the internal findings were unavailable for review. These observations call into question the laboratory's ability to: 1) perform asbestos testing by stereomicroscope and PLM; and 2) respond with appropriate corrective actions to internal and external audit findings and to properly document those responses.

New Laboratory Deficiencies

The February 2004 audit report indicates 5 new findings not identified in the previous audit. These findings included deficiencies in the areas of analytical procedure, documentation, and QA practices. Specifically, potential for cross-contamination was a factor for several analytical techniques. Most significantly, however, the RJ Lee Group, Inc.—San Leandro facility failed to perform required QA measures for TEM such as instrument calibration procedures and performance of QC samples. These are serious deficiencies. These observations call into question the laboratory's ability to perform asbestos testing by TEM.

Overall Assessment

The audit concludes: "Procedural weaknesses were observed with regard to the security of the facility, sample receipt, sample tracking, record keeping, sample preparation, instrument calibration, and the quality management system. While the laboratory was generally compliant with regard to meeting the method requirements, the relatively large number of repeat

deficiencies (35%) indicate that the responsiveness on the part of management to address identified deficiencies can be improved." The February 2004 audit report indicates that staff personnel would benefit from retraining, but places the primary onus on the laboratory management for the noted deficiencies. On the basis of this repeat audit report, the ongoing deficiencies identified at this facility are serious enough that I could not in good conscience indicate that the San Leandro Laboratory be used for asbestos analyses at Superfund sites.

Section 1.4 July 2004 OSRTI Memo—San Leandro

In regard to the San Leandro facility, the OSRTI 2004 memo indicates that "improvements have been made to operations...since the 2001 audit". A comparison of the 2004 and 2001 audit reports generally confirms this; however, the 2004 OSRTI memo provides an additional list of improvements made. They were: "1) the hiring of a laboratory manager dedicated to improving laboratory operations; 2) incorporation of instrument dedicated electronic data entry stations programmed for mandatory entry and archiving of key data parameters; 3) the standardization of method Standard Operating Procedures (SOPs); 4) extensive personnel training; and 5) the direct involvement of corporate quality assurance staff from the Monroeville corporate facility." Since the San Leandro facility was not required to provide a response to either of the audit findings and ASB reports no such response/corrective action documents are available, it is unclear how information on these types of global improvements made to the laboratory were obtained by EPA and ultimately reported in the 2004 OSRTI memo.

Regardless, it is curious that EPA would state that: "...deficiencies noted in this latest audit do not preclude ASB from placing the San Leandro facility on its list of **approved** asbestos testing laboratories" (emphasis added). This statement is not consistent with caveats provided in either the last paragraph of the 2004 OSRTI memo or on an EPA website's list of laboratories. The caveats on the internal EPA website state that inclusion of a laboratory on the list does not imply certification, and nowhere is the word "approved" used to characterize the laboratories on that list. Use of the word "approved" in the 2004 OSRTI memo goes beyond what is appropriate and implies the San Leandro facility has a certain asbestos testing capability. Such a capability by this laboratory is not supported by the actual findings of either of the two audit reports.

Section 2. RJ Lee, Inc.—Monroeville Facility

In March 2004 ASB visited the RJ Lee Group, Inc.—Monroeville facility. A report for the audit was prepared in April 2004. While certainly not a contractual requirement, the reason for the visit is not given in the report. The scope of the audit included evaluations of several analytical techniques including PLM, PCM, and TEM. Region 8 assessed the April 2004 audit report for several components. These include an assessment of: the facility's ability to perform asbestos analysis; the adequacy of the supporting QA/QC program; and the applicability of the laboratory audit as it relates to analyses performed on Libby Asbestos Site samples by the Monroeville facility around 2000 and 2001.

Three (3) observations are noted in the audit report. In general this should be taken as an indication that most aspects of laboratory activities are being carried out in accord with laboratory-specific SOPs. Deficiencies were identified in the areas of: sample handling and preparation; sample analysis; documentation; and QA practices. Specifically, potential for cross-contamination was a factor for several analytical techniques. Additionally, the RJ Lee Group, Inc.—Monroeville facility failed to consistently identify or record on the TEM count sheets the reference numbers of EDXA spectra and SAED patterns. This particular observation is consistent with the state of raw data packages of asbestos analyses performed on Libby Asbestos site samples by RJ Lee Group, Inc.—Monroeville around 2000 and 2001. These observations call into question the laboratory's ability to accurately record, and therefore, represent the results of asbestos testing by TEM. It should be noted that the raw data packages audited in 2004 do not represent samples collected from EPA Superfund sites.

The audit report concludes: "All deficiencies identified from this audit were minor in nature and should be readily correctable." The report also states: "Overall, the on-site audit revealed that the laboratory has sufficient analytical and storage space, analytical equipment, and competent staff to effectively analyze a moderate number of samples. The personnel appeared to be proficient and knowledgeable with regard to the applicable sample handling, analysis, and reporting procedures. All staff were very cooperative, and readily answered all questions posed by the on-site audit team. Finally, the management of the laboratory was responsive to the identified deficiencies, and appeared to be dedicated to providing quality deliverables." Based upon the audit findings *alone*, I would conclude similarly. That is, without having the direct experience of observing incomplete and improperly documented raw data packages obtained from the Libby Asbestos Superfund Site, I too, would have concluded the Monroeville facility capable of reliably testing for asbestos by TEM. However, Region 8 has direct experience to indicate otherwise.

Applicability to Analyses Performed at the Libby Site

The April 2004 audit was performed many years following the timeframe when the Monroeville facility analyzed samples from Libby. Potential for: staff changes, changes in fiber identification and counting procedure policy, and changes in general laboratory practices all point to the conclusion that this audit cannot in any way be used to retroactively assess quality and accuracy of data collected prior to March 2004. Interestingly, this most recent audit revealed the Monroeville facility's practice of poor documentation regarding EDXA spectra and SAED patterns. In light of this, the RJ Lee Group, Inc.—Monroeville facility has an on-going deficiency in its documentation practices for TEM. This fact alone would lead me to question the Monroeville facility's capability to perform asbestos analysis for TEM.

Section 2.1 July 2004 OSRTI Memo—Monroeville

The 2004 OSRTI memo does not appear to accurately reflect the audit findings at the Monroeville facility. For example, the 2004 OSRTI memo states: "ASB auditors were hard pressed to find any deficiencies at this corporate asbestos testing laboratory." Though few in number, deficiencies were indeed observed at the Monroeville facility. Left uncorrected, these deficiencies could result in data of unknown quality.

The memo also states: "This facility could easily be considered among the most capable of those laboratories audited and approved by ASB for Superfund asbestos testing needs." This conclusion is inappropriate on several points. First, as discussed in Section 1.4 for the San Leandro section of the 2004 OSRTI memo, it is inappropriate to use the word "approved" to describe the EPA's internal list of analytical labs and use of "approved" in the 2004 OSRTI memo implies more about the lab's capabilities than is appropriate. Second, as I understand the purpose of the EPA's internal list of analytical labs, it is inappropriate to rank the laboratories provided on the list as no scoring system is available to do so. Finally, this statement does not appear in the audit and cannot be substantiated through documentation.

The memo further states: "Raw data is managed by instrument dedicated data entry PDAs coupled to a LIMS server which makes reporting of incomplete results almost impossible." It is unclear how this statement made its way into the 2004 OSRTI memo. Given that 1 of the 3 audit findings was a documentation problem associated with raw data; it is inaccurate, misleading, and improper to state "...which makes reporting of incomplete results almost impossible."

Conclusions

Statements in the 2003 OERR memo are substantiated by documentation provided in the 2001 audit report for the RJ Lee Group, Inc.—San Leandro facility. Based upon the documentation available, critical statements included in the 2004 OSRTI update memo appear to be either unsubstantiated and/or do not accurately reflect the contents of the audit reports.

Further, it is my understanding that the original intent of EPA's internal list was to identify laboratories that responded to and successfully met contract requirements outlined in ASB's request for bid. As part of that bid request, ASB did not require any of the laboratories on EPA's internal list to provide documentation outlining the corrective actions taken in response to ASB's audit findings. Therefore, aside from the RJ Lee Group, Inc. facilities, none of the other laboratories on EPA's internal list have been given an opportunity to provide the Agency with information regarding corrective actions taken in response to any previous ASB's audit findings. Because of this and because comparison review criteria have not been established, any effort to judge or compare competencies between laboratories on the list is not appropriate. The RJ Lee Group, Inc. did not respond to EPA's bid request, thus it is not clear why they have been placed on this list at this time.